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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/058,589	04/10/98	KIMBER I	138.41.US01

027194
HM12/0606
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EXAMINER	
WANG, S	
ART UNIT	PAPER NUMBER
1617	23

DATE MAILED: 06/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/058,589	KIMBER ET AL.	
	Examin r	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-18 and 21-25* is/are pending in the application.

4a) Of the above claim(s) *11 and 15-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *5-10,12-14 and 21-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

1. The request filed on April 9, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/058589 is acceptable and a CPA has been established. An action on the CPA follows.

2. Applicants' election in the parent application is presumed to carry over to the instant CPA since applicants have not indicated a contrary intention. Therefore, Claims 11 and 15-18 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

Claim Rejections 35 U.S.C. 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 5-7, 9, 12-14 and 21-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Conneely et al. (U.S. Patent 6,111,081).

5. Conneely teaches the method for treatment of psoriasis, contact dermatitis, UV-induced inflammation or diaper rash by administering a variant of lactoferrin. See, column 8, lines 37-63.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims Rejection 35 U.S.C. – 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 5-10, 12-14 and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conneely et al. (U.S. Patent 6,111,081).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference

under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2)..

6. Conneely teaches the method for treatment of psoriasis, contact dermatitis, UV-induced inflammation or diaper rash by administering a variant of lactoferrin. See, column 8, lines 37-63.

3. Conneely does not teach expressly the employment of natural lactoferrin or the active fragment of lactoferrin for the treatment. However, lactoferrin variants are known to have the same bioactivity as lactoferrin. See, column 2, lines 53-58. Therefore, natural lactoferrin and its bioactive fragments would have been reasonably expected to be similarly useful for treatment of the dermal disorders.

Claims 5-10,12-14 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teng et al. (of record) in view of Britigan (Advances in Experimental Medicine and Biology, Vol. 357, page 143-156, 1994), Greff (CAPlus Abstract, AN 1988:226674) and De Lacharriere et al. (US Patent 5,658,581).

4. Teng et al teach a method of treating dermal inflammatory disorder of human comprising the step of administering a pharmaceutically effective amount of lactoferrin product. See, particularly, page 4, lines 21-30.

5. Teng et al. does not teach expressly the treatment of the particular dermal disorder herein or the employment of biological analog or fragments of lactoferrin.

However, Britigan teaches generally that lactoferrin are known to be useful as an anti-inflammatory agent. See, particularly, page 151, the summary and conclusion. Greff teaches that lactoferrin are known to be useful for delay the aging of skin, soothing inflammation, including UV-induced inflammation (solar erythema). See, the abstract. De Lacharriere et al. teach that TNF antagonists, lactoferrin is known to be useful for treating or preventing skin inflammation induced by certain cosmetic or pharmaceutical active agent.

Therefore, Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ lactoferrin product for treatment dermal disorder, particularly, skin inflammation, including UV-induced inflammation, or for delay skin aging.

A person of ordinary skill in the art would have been motivated to employ lactoferrin product for treatment dermal disorder, particularly, skin inflammation, including UV-induced inflammation, or for delay skin aging because lactoferrin is well-known to be useful for anti-inflammation, and is further known particularly useful for treatment of skin inflammation, solar erythema, and skin aging delay. Regardin the functional limitation in claim 7, i.e., "a local immune response characterized by increased production of TNF-α" and in claim 21, "a dermal inflammatory response that is characterized by accumulation of dendritic cell in lymph nodes" , note such limitation is not seen to render the claimed invention any patentable weight since the ultimate method, e.g., administering lactoferrin to person with dermal disorder such as contact dermatitis, UV-induced inflammation, psoriasis, skin aging or diaper rash, is not further limited

by such functional language. Further, a method for treatment of a symptom would have been reasonably expected to be effective for the treatment of the symptom despite the underline etiology that cause the symptom.

6. Claims 5-10,12-14 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teng et al. (of record) in view of Nuijens et al (of record) and Enk et al.(Proc. Natl. Acad. Sci. USA, Vol 89, pp 1398-1402, provided in IDS of August, 6, 1998), Database WPI AN 95-340208 (IDS October 2, 1998) and Penco et al. (of record).

7. Teng et al teach a method of treating dermal inflammatory disorder of human comprising the step of administering a pharmaceutically effective amount of lactoferrin product. See, particularly, page 4, lines 21-30.

8. Teng et al. do not teach expressly the particular inflammatory dermal disorders herein or the employment of biological analog or fragments of lactoferrin.

9. However, Nuijens et al. teach that lactoferrin reduces the production of IL-1beta and TNF alpha and inhibit proliferation. See, particularly, page 287, third paragraph. Enk et al. teach that both IL-1beta and TNFalpha are responsible for promoting inflammatory activity, including the allergen-induced inflammatory activity. See, particularly, the abstract. Penco et al. further teach that lactoferrin inhibits the activity of IL-1beta. See, the abstract. Database WPI AN 95-340208 disclose that lactoferrin analog and fragments are known to be similarly useful as lactoferrin in treating dermal disorder. See the abstract.

Therefore it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use the method of Teng et al. for inhibiting

the dermal inflammatory activity of IL-1beta or to employ the lactoferrin active biological analog or active fragments in Teng's method.

A person of ordinary skill in the art would have been motivated to use the method of Teng et al. for inhibiting the dermal inflammatory activity of IL-1beta or to employ the lactoferrin biological analog or active fragments in Teng's method because lactoferrin is known for reducing the production of IL-1beta and TNF alpha and inhibiting the activity of IL-1beta and the lactoferrin active biological analog or active fragments are known to be similarly useful for treatment of dermal disorder. Regarding claim 21-25, note the detailed biochemical process related to the symptomology is not seen to render unobviousness to an otherwise old and well-known method. The employment of lactoferrin for treatment of skin inflammatory disorder is old and well known as discussed above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Shengjun Wang
AU 1617
~~January 3~~, 2001
6-1,

RUSSELL TRAVERS
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